

REMARKS

Claims 1-26 are pending in the application and are currently rejected. Claims 1, 12-16 and 22 have been amended. Claim 11 has been cancelled. In light of the amendments and remarks herein, reconsideration of claims 1-10 and 12-26 is respectfully requested.

Amendments to the Specification

The Specification has been amended to address the Examiner's objections. No new matter has been added to the Specification.

Amendments to the Claims

While Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants, the claims have nonetheless been amended as follows in order to expedite the allowance of the application. The amendments are therefore made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendments, such as through continuation practice.

Claim 1 is amended to recite an apparatus having at least one thermally conductive element configured to extract heat from the emitter. Support for this amendment is found in the specification at, e.g., paragraphs 065 and 074-077, as well as in original claim 11.

Claims 11 is cancelled.

Claims 12-15 are amended to change their dependency from Claim 11 to Claim 1.

Claim 16 is amended to provide the missing antecedent basis.

Claim 22 is amended to correct a typographical error.

As such, the amendments to claims 1, 11-16 and 17 do not add new matter.

Double Patenting

The Examiner provisionally rejected claims 1-7, 9-16, 18, 19, and 21-26 based on obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6-9, 22-29, 32, 33, and 35-40 of copending U.S. Patent Application No. 10/776,686 (the “‘686 Application”).

The differences between Claim 1 in the present application and Claim 1 of the ‘686 Application are not obvious. Each claimed invention is different in kind and is, therefore, patentably distinct. For example, as presently amended, Claim 1 of the present application recites a body that is “adapted to conform to the shape of at least a portion of the oral cavity” as well as “at least one thermally conductive element configured to extract heat from the emitter.” On the other hand, Claim 1 of the ‘686 Application, from which all other cited claims from the ‘686 Application depend, recites “at least one radiation emitting element coupled to the body to selectively irradiate a portion of the oral cavity with phototherapeutic radiation along multiple directions.” These two independent claims are directed to two independent inventions. The present application claims a device that is capable of conforming to all or a portion of the oral cavity, e.g., a mouthpiece, and that provides at least one thermally conductive element configured to extract heat from the emitter.¹ The ‘686 Application as filed claims a device capable of emitting radiation in multiple directions to, e.g., selectively direct optical radiation delivered from an oral appliance to different regions of the oral cavity depending on the desired treatment regimen. (See ‘686 Application ¶ 080.) Claims 3, 4, 6-9, 22-29, 32, 33, and 35-40 of the ‘686 Application also do not constitute double patenting, because they incorporate the non-obvious limitations of Claim 1, which are patentably distinct over Claim 1 of the present Application.

Claims 2-7, 9-16, 18, 19, and 21-26 of the present invention are patentably distinct for the same reasons that Claim 1 is patentably distinct.

¹ Unless specifically noted otherwise, any use of examples in this response is intended to be exemplary only and is not intended to limit the scope of any pending claim or any claim that may issue from this application.

The Examiner also provisionally rejected claims 1-4, 6-16 and 22-26 based on obviousness-type double patenting as being unpatentable over claims 1-5, 7-9, 22-29 and 36-39 of copending Application No. 10/776,687 (the “‘687 Application”).

The differences between Claim 1 in the present application and Claim 1 of the ‘687 Application are not obvious. Claim 1 of the ‘687 Application, from which each of the other cited claims depend, recites an “emitter being capable of delivering radiation to a region of facial tissue.” These two Applications are directed to two independent inventions. As noted above, the present application claims a device that is capable of conforming to all or a portion of the oral cavity and that provides at least one thermally conductive element configured to extract heat from the emitter. On the other hand, the ‘687 Application claims a device capable of emitting radiation to facial tissue from the oral cavity to, e.g., treat acne by directly radiating from within the oral cavity out toward the target tissue instead of treating acne by radiating the affected skin. (See ‘687 Application ¶ 0131.) Dependent claims 2-5, 7-9, 22-29 and 36-39 of the ‘687 Application also do not constitute double patenting, because they incorporate the non-obvious limitations of Claim 1, which are patentably distinct over Claim 1 of the present Application.

Claims 2-4, 6-16 and 22-26 of the present Application are patentably distinct for the same reasons that Claim 1 is patentably distinct.

The Examiner also provisionally rejected claims 1-4, 6-16 and 18-26 based on obviousness-type double patenting as being unpatentable over claims 1-5, 9-23, 25-32 and 34-46 of copending Application No. 10/777,022 (the “‘022 Application”).

The differences between Claim 1 in the present application and Claim 1 of the ‘022 Application are not obvious. Each claimed invention is different in kind and is, therefore, patentably distinct. Claim 1 of the ‘022 Application, from which each of Claims 2-5, 9-23, 25-32 and 34-46 depend, recites “at least one radiation emitter coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation *in at least two separate spectral bands*.” These two independent claims are directed to two independent inventions. The present application claims a device that is capable of conforming to all or a portion of the oral cavity and that provides at least one thermally conductive element configured to extract heat from the

emitter. The '022 Application a device that is capable of irradiating tissue in the oral cavity using distinct spectral bands to, e.g., "treat the same conditions more effectively or to treat two different conditions." (See Application ¶ 086.) Claims 1-5, 7-9, 22-29 and 36-39 of the '022 Application also do not constitute double patenting, because they incorporate the non-obvious limitations of Claim 1, which are patentably distinct over Claim 1 of the present Application.

Claims 2-4, 6-16 and 18-26 of the present invention are patentably distinct for the same reasons that Claim 1 is patentably distinct.

Claim Rejections - 35 U.S.C. § 112

Claim 16 was rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants have amended that claim to provide the missing antecedent basis.

Claim Rejections - 35 U.S.C. § 102

Claims 1-8, 10, 11, 16, 18, 19-22 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/06456 to Chen et al. (herein "Chen"). These claims are novel, however, because Chen fails to teach or suggest the elements recited in the amended claims. Amended claim 1 recites "at least one thermally conductive element configured to extract heat from the emitter." Chen does not teach heat dissipation, and does not disclose a device having the ability to extract heat.

Claims 2-8, 10, 11, 16, 18, 19-22 and 26 are novel for at least the same reasons that Claim 1 is novel.

With respect to Claim 8, Chen does not disclose, either explicitly or implicitly, the use of an optical filter for selecting a spectral band of radiation. Chen teaches applying a photoreactive agent and applying light that has a corresponding waveband. Specifically, Chen states:

Each type of photoreactive agent has a characteristic absorption waveband or range of wavelengths that are absorbed. Light having a corresponding waveband or range of wavelengths is then applied by fixture 20.

(See Chen at page 7, lines 2-4.) Chen does not disclose the application of multiple photoreactive agents at one time. (See, e.g., Chen, Abstract.) Further, Chen also does not disclose that, to correspond to the characteristic waveband of the photoreactive agent, the applied waveband must precisely correspond the absorption waveband of the photoreactive agent, as opposed to, for example, provide a broader range of light than the characteristic absorption waveband. Therefore, Chen cannot be said to inherently teach the use of filters, whether or not using a polychromatic source, because there is no disclosure that the applied waveband must be altered or limited. Chen is silent as to whether such a filter would be required or beneficial.

With respect to Claim 11, Chen does not discuss either temperature or heat dissipation. Chen also does not disclose the use of thermally conductive materials to dissipate heat. Rather, Chen discloses only the use of polymers, such as and optically transparent polyurethane or similar plastic. (See Chen page 7, lines 17-20.) Such polymers are typically very poor conductors of heat. For example, as shown in attached Exhibit A (excerpt from Rodriguez, Principles of Polymer Systems, 2nd edition, McGraw Hill, New York, 1982, p. 266) the thermal conductivity of most polymers is around $4.1 \times 10^{-4} \text{ cal sec}^{-1} \text{ cm}^{-1} \text{ K}^{-1}$ (this is equivalent to about $0.1 \text{ Btu/ft}^{-1} \text{ hr}^{-1} \text{ F}^{-1}$, which is midpoint of the range of thermal conductivity values cited by Rodriguez). In comparison, aluminum, which is named as an exemplary heat sink material in the application (see paragraph 074 of the Application), is *approximately one-thousand times more thermally conductive* than a typical polymer (i.e., about $5 \times 10^{-1} \text{ cal sec}^{-1} \text{ cm}^{-1} \text{ K}^{-1}$ as shown in Exhibit B, excerpted from Bird, Stewart, Lightfoot, Transport Phenomena, John Wiley & Sons, Inc., New York, 1960, p. 249).

Accordingly Claims 1-8, 10, 11, 16, 18, 19-22 and 26 are novel and patentable over Chen.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 9-10 and 24

Claims 1, 9-10 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller (herein “Muller”) in view of U.S. Patent No. 5,133,102 to Sakuma (herein “Sakuma”).² The claims, however, are patentable, because even when combined Muller and Sakuma do not provide all of the elements of the claims.

Claim 1 is directed to an apparatus for treating the skin, comprising a body sized and shaped so as to fit at least partially in a user’s mouth and adapted to conform to the shape of at least a portion of the oral cavity; at least one radiation emitter coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation; and at least one thermally conductive element configured to extract heat from the emitter.

Muller, the primary reference, is directed to a toothbrush head suitable to direct incident radiation toward a surface of a tooth and to collect emitted radiation from the surface of the tooth. (See Muller, Abstract.) Muller does not teach a body “adapted to conform to the shape of at least a portion of the oral cavity” or “at least one thermally conductive element configured to extract heat from the emitter” as required by Claim 1. Muller teaches a toothbrush head having “a monolithic body of transparent plastic material” and having bristles “fixed” into the head. (See Muller Col. 13, lines 25-28 and 45.) Muller does not teach a body that conforms to a portion of the oral cavity. Examiner at page 6 of the Office Action states that Muller supplies this element, because the bristles conform to the teeth. However, Claim 1 requires that the structure that conforms to a portion of the oral cavity is the body itself, and not the bristles extending from the body. Muller teaches a body that is distinct from the bristles, and thus, does not satisfy that element of the claim.

Sakuma does not supply the teachings that are missing from the claims. Sakuma does not teach a conforming body or at least one thermally conductive element configured to extract heat from the emitter as required by claim 1. Sakuma also does not teach a sensor, a controller or a

² Note that in the Office Action dated September 30, 2005, the Examiner cited U.S. Patent 5,133,120, which is actually a patent issued to Kawakami that deals with printed wiring boards. Therefore, the applicants have presumed that the Examiner intended to reference U.S. Patent 5,133,102 to Sakuma, which concerns an electronic toothbrush, and that the last two digits in the patent number were simply transposed.

diagnostic sensor as required by claims 9 and 10. Sakuma teaches a simple circuit that is closed by the gripping of the handle of the toothbrush and the touching of the bristles to the teeth. The complete circuit causes “a current which passes through the user’s hand and body flows into the surface of the teeth via the dental pulp tissue and tooth tissue proper.” (See Sakuma Col. 4, lines 4-9.) The “flow of electric current causes the protein organic ions of plaque on the surfaces of the teeth to become affixed to the toothbrush.” (See Sakuma Col. 4, lines 4-9.) Sakuma does not emit radiation onto the teeth and, thus, does not include a controller that controls the emitter. Instead, the LED that is disclosed in Sakuma is an alarm to alert the user “that the toothbrush is operating.” (See Sakuma, Abstract.)

Given the very different principles of operation between Muller and Sakuma, it would not be obvious to combine the references absent some specific teaching, which neither reference provides. Furthermore, even if combined, the references do not disclose all of the elements as recited in amended Claim 1.

Claims 1, 11, 13, 15 and 23

Claims 1, 11 (now cancelled), 13, 15, and 23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller in view of U.S. Patent No. 4,333,197 to Kuris (herein “Kuris”). The claims, however, are patentable, because there is no suggestion or motivation to modify the toothbrush head of Muller with the ultrasonic toothbrush of Kuris. Further, even when combined, Muller and Kuris do not disclose all of the required elements of the claims.

Muller, as discussed above, does not teach all of the elements of Claim 1. Specifically, Muller does not teach or disclose the removal of heat or the control of temperature. The Examiner states at page 6 of the Office Action that heat transfer in the device in Muller is inherent because virtually all materials have some heat transfer capacity. However, even if true, not all materials are suitable for extracting heat. Applicants submit that it is commonly known in the art that the thermal conductivity in many materials is so low that they are considered to be insulators that effectively do not conduct heat in any meaningful sense. On the other hand, the Applicants specifically disclose an embodiment with structures having sufficient thermal

conductivity to facilitate the conduction of heat. For example, in paragraph 074, the Applicants state:

An LED, a laser diode, or a microlamp can generate heat energy that is up to 20 times higher than the generated optical energy. To accommodate unwanted waste heat, the light emitting oral appliance can include heat transfer and/or cooling mechanisms. For example, head portion 12 of the exemplary light emitting toothbrush can be at least partially formed of a heat conducting material for dissipating heat generated by the radiation source. For example, with reference to FIG. 2B, the head portion 12 can include a head frame 38 that is constructed from a material having high thermal conductivity and/or good heat capacitance and is thermally coupled to the radiation source 18 to extract heat therefrom.

In contrast, Muller is silent both as to the need to remove waste heat in his device and as to the thermal conductivity of the structures included in his device. The ability to remove heat, therefore, is not inherent in Muller.

Kuris also does not disclose “at least one thermally conductive element configured to extract heat from the emitter” as required by the claims. The electronic components to which Kuris refers are not contained in the ultrasonic toothbrush. Instead, the components are part of a display case, and not the ultrasonic toothbrush itself. The display case is designed to be mounted on a wall or placed on a table. Thus, at best, Kuris teaches heat transfer from electrical components associated with the input power transformer 52 in the display case and not from either the transducer motor 60 or any ultrasound emitter located in Kuris’ toothbrush. Thus, Kuris does not teach the heat transfer elements of claims 13 and 15.

Similarly, Kuris does not teach the combination of an emitter with an ultrasound generator as required in claim 23. Kuris teaches only the use of ultrasonic energy for use in a toothbrush. Kuris does not teach the use of an ultrasound generator energy in a device having a body adapted to conform to at least a portion of the oral cavity, and Kuris does not teach the use of an emitter in combination with an ultrasound generator. There is no teaching or suggestion in either Muller or Kuris to combine these elements, or that such a combination would compliment the hygienic process as stated at page 7 of the Office Action. Therefore, absent some stated motivation to combine the references, the combination is not obvious.

Claims 12 and 14

Claims 12 and 14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller in view of Kuris in further view of U.S. Patent 6,425,912 to Knowlton ("Knowlton"). The claims, however, are patentable, because there is no suggestion or motivation to modify the optical toothbrush head of Muller with the ultrasonic toothbrush of Kuris and the skin device of Knowlton.

With respect to claims 12 and 14, which are dependent on amended claim 1, the combination of Muller and Kuris has the same deficiencies discussed above with regard to claims 1, 13 and 15. Furthermore, there is no teaching or motivation that is evident in the references for combining Knowlton's cooling system with the toothbrush devices of Muller and Kuris. Knowlton uses high energy levels to reshape collagen-containing tissue, and the cooling mechanism provides a means to protect the collagen-containing tissue from thermal damage.

Fluid delivery device 13 is configured to deliver a heat transfer media 15 (also called a cooling media 15, flowable media 15 or fluid 15) to tissue interface 21, that serves to dissipate sufficient heat from the skin and underlying tissue at or near tissue interface 21 during the delivery of energy at or near this site so as to prevent or reduce thermal damage including burning and blistering. Similarly, fluid delivery device 13 may also deliver fluid 15 to and dissipate heat from energy delivery device 18 and/or template 12 to achieve a similar result.

(See, e.g., Knowlton Col. 5, lines 4-13.) There is no teaching from Muller or Kuris that suggests that the toothbrush devices of Muller or Kuris operate at sufficiently high power that either tissue may be thermally damaged, including burning and blistering, or that cooling as in Knowlton is either required or beneficial. Thus, there is no motivation to combine the references.

Claim 17

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Chen in view of U.S. Patent 4,862,903 to Campbell ("Campbell"). The claim, however, is patentable, because there is no suggestion or motivation to modify the periodontal device of Chen with the snorkeling device of Campbell.

As discussed above, Chen fails to disclose all of the elements of Claim 1, including the lumen disclosed in claim 17. Campbell discloses an improved mouthpiece for use with a snorkel or regulator. (See Campbell, Abstract.) Specifically, Campbell discloses a mouthpiece that allows the user to hold a snorkel or regulator in place by evenly distributing the load across the space between the lips and teeth. (See, e.g., Campbell Col. 5, lines 6-14.) Campbell does not disclose the use of the mouthpiece for use in dental applications. The problem that Campbell addresses is associated with the manner in which the snorkel or other diving apparatus is secured in the mouth, and does not address an improvement in the breathing passage itself. Further, Campbell only discusses the invention in the context of providing an improved mouthpiece for snorkeling or other forms diving, and Campbell does not disclose or suggest using the device for other purposes.

Furthermore, Chen teaches away from the need to provide the lumen by stating that the preferred practice is to divide treatments to first treat the upper teeth and then the lower teeth to improve patient comfort. (Chen page 5:23-26.) Due to that and other teachings of Chen, the mouthpiece in Chen would not appear benefit from the inclusion of a lumen to facilitate breathing.

As such, there is no teaching or motivation to combine the snorkeling mouthpiece of Campbell the device for treating the oral cavity in Chen.

Claims 1 and 25

Claims 1 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller in view of U.S. Patent 5,658,148 to Neuberger et al. ("Neuberger"). The claim, however, is patentable, because there is no suggestion or motivation to combine the toothbrush of Muller with the dental device of Neuberger, and, even if combined, would not provide all of the claimed elements.

As discussed above, Muller fails to disclose all of the elements of Claim 1. Furthermore, though the Examiner states that it would be obvious to combine Neuberger with Muller to achieve the drug deliver port as recited in Claim 25, Neuberger does not supply the missing

claim elements. The pressurized fluid system of Neuberger cited in the Office Action at page 8 functions in a manner that is inconsistent with the disclosure of Muller, and there is no motivation to combine the two devices. For example, Neuberger provides fluids under high pressure to facilitate the emission of laser radiation, not merely to deliver a drug through a port.

Water or liquid passage 52 carries water or liquid under pressure to fiber end 53. Water or liquid passes through passage 52, over surface of fiber end 53, and then through liquid and laser radiation delivery opening 55 to any proximal oral area to be cleaned or treated. Plastic brush 50 is designed to be safe for home use by the fact that laser radiation coming to fiber end 53 will be reflected harmlessly upward into plastic brush 50 if no liquid is being forced through liquid passage 52. This is due to angle 54 which creates a reflective surface because air and optical fiber 51 have substantially different n. When liquid is passing over the surface of fiber end 53 laser radiation will pass through substantially parallel to the longitudinal axis of optical fiber 51, thereby being delivered to oral areas to be cleaned or treated via opening 55 with the liquid that came through passage 52. This occurs because the difference in n between optical fiber 51 and a liquid or water is low enough that fiber end 53 is now a refractive, rather than a reflective, surface.

(See Neuberger Col. 4, lines 7-25.) Thus, there is no explicit motivation to attempt to include the high pressure water flow device of Neuberger that is cited by the Examiner in the device disclosed by Muller, and the principle of operation of the device in Neuberger is too different to be useful with Muller.

Application No. 10/777,020
Reply to Office action of September 30, 2005

Group Art Unit: 3739
Examiner: Henry M. Johnson III
Atty. Docket No. 105090-234

CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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